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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/732,408	12/09/1996	JOHANNES REINMULLER	HUBR1099PFFM	7906

7590 03/10/2005

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/732,408	Applicant(s) REINMULLER, JOHANNES	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 129-181 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 129-181 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Objections

Claim 157 is objected to for being unclear, since the claim was amended and now the language presents poor grammar. It appears it should read "fat on the surface".

Claims 171-174 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 129 and 147 recite the "spaghetti-like strand" is solid, therefore the limitation of the strand being "solid" in claims 171-174 does not add any new limitation.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 129-132, 135-141, 147, 149, 152-155, 160, 167-181 are rejected under 35 U.S.C. 102(e) as being anticipated by Henley (5534023). Fig. 1 shows a medical implant with a plurality of connected strands of material **14** and an outer covering **11**. Henley discloses the covering is a silicone rubber, col. 4, lines 8-9. Henley also discloses the beads inside have extrudate chains **14** that the Examiner is interpreting as "spaghetti-like strands," which are made of silicone, col. 4, lines 30-33. It is inherent that silicone is hydrophobic. With respect to claims 171-174, Fig. 2 shows the strands are solid that are used to connect beads. Henley discloses the method of using the implant for implantation and it is placed at a soft tissue site, col. 3, lines 60-65. Henley

discloses lubricants to reduce friction can also be added, such as swellable ones or a polysaccharide such as dextran, col. 6, lines 22-26. Please note that anything can be considered "wetable". The examiner is interpreting the claimed elements "continuous solid strands" in this way: since all the strands are joined it can be considered to be continuous. Claims in a pending application should be given their broadest reasonable interpretation. *In re Hyatt* (CAFC) 54 USPQ2d 1664 (2000). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 133, 134, 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Fisher (5496367). Henley '023 is explained as before. However, Henley does not disclose the use of plastic for the strand material. Fisher discloses the use of plastic for structural material enclosed in an implant, col. 3, lines 18-22. It would have been obvious to one of ordinary skill in the art to substitute materials and use plastic as taught by Fisher in the implant of Henley such that it provides a little more rigidity or firmness.

Claims 142, 144-146, 148, 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Shimizu (5607590). Henley '023 is explained as before. However, Henley does not disclose the surface is hydrophilized. Shimizu teaches that silicone surfaces can be hydrophilized such that it increases the affinity for living tissue or potential tissue ingrowth, col. 1, lines 49, 50, 55-60. It would have been

obvious to one of ordinary skill in the art to use a hydrophilized surface as taught by Shimizu with the implant of Henley such that the prosthesis is able to be secured within the body and not have shifting.

Claims 156,157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Perry et al. (5282857). Henley is explained supra. However, Henley does not disclose using fat or oil as a lubricant. Perry et al. teach that fats or oils in the form of glycerides are used in implants, col. 3, lines 1-4. It would have been obvious to one of ordinary skill in the art to use a fat or oil that wets a surface of the implant for lubrication as taught by Perry with the implant of Henley in order to reduce friction and permit a more natural movement within the shell.

Claim 143,161,162 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Taylor (4657553). Henley is explained supra. However, Henley does not disclose the use of polysaccharides or polydimethylsiloxane as the implant material. Taylor teaches that polysaccharides are used in soft tissue implants and can be hydrophilic, col. 1, lines 55-57. Taylor also teaches that polydimethylsiloxane is used in constructing medical implant material, col. 4, lines 37-44. It would have been obvious to one of ordinary skill in the art to use a polysaccharide or polydimethylsiloxane as the implant material as taught by Taylor for the implant of Henley because of the suitability of these materials in medical uses. Polysaccharides are not harmful if leakage does occur.

Claim 159 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Shimizu '590 as applied to claim 148 above, and further in view of Fisher

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'367. Henley as modified by Shimizu is explained supra. However, Henley in view of Shimizu do not disclose plastic as the implant material. Fisher is explained supra. It would have been obvious to one of ordinary skill in the art to use plastic as an implant material as taught by Fisher for the implant of Henley as modified by Shimizu in order to provide a little more firmness to the implant's feel.

Claim 163 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Fisher '367 as applied to claim 158 above, and further in view of Chapman (4348329). Henley as modified by Fisher is explained supra. However, Henley in view of Fisher do not disclose cuprophane as the implant material. Chapman teaches that polymers or "plastic" used in implants have coatings that are biocompatible, col. 6, lines 32-36,49-54 and cuprophane is one material used (col. 13, lines 9,12). It would have been obvious to one of ordinary skill in the art to use cuprophane as an implant material as taught by Chapman for the implant of Henley as modified by Fisher in order to reduce cell membrane damage.

Claims 164-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Ledergerber (EP 322194). Henley is explained supra. However, Henley does not disclose a foam structure in the implant or X-ray medium incorporated in the implant. Ledergerber teaches that foam can be used in the implant, col. 4, lines 8-18. Ledergerber additionally teaches that an x-ray contrast medium can be incorporated into the material, col. 12, lines 53-58. It would have been obvious to one of ordinary skill in the art to use a foam structure or a contrast medium in the implant as taught by Ledergerber with the implant of Henley such that it may be less dense as a

result of using foam so it does not feel too heavy for the patient and is easily detected by imaging.

Response to Arguments

Applicant's arguments filed 9/1/04 have been fully considered but they are not persuasive. Henley does disclose a continuous strand of material that is connected together. Fig. 2 shows the material extends and forms a continuous strand with the beads. Also the sections established as connectors (14) in Henley can reasonably be considered as "continuous" because no special meaning or amount has been defined in the Applicant's disclosure to define "continuous". The Examiner also interprets "solid" as something not liquid.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Brian E. Pellegrino".